

REMARKS

The claims added by this preliminary amendment are copied from U.S. Patent 6,572,576, issued on June 3, 2003. It is believed that no new claim is the same as or substantially the same as any claim in US Patent Application Publication 2003/0009123 that was published on January 9, 2003 – which is before the filing of this application. *See* 35 U.S.C. §135(b)(2). The following table correlates the claims added by this preliminary amendment to the claims of the '576 Patent and shows the support in this application for the copied claims:

Application Claims	'576 Patent Claims	Support in This Application For Claim (References to col. and line of parent patent 6,585,675).
37	1	<p>Col. 19:47-51: The controller CPU regulates the pump speeds by commanding a motor controller 702 to set the rotational speed of the blood pump 113 to a certain speed specified by the controller CPU.</p> <p>Col. 16: 60-64: The PIFF pressure controller 501 controls the withdrawal pressure to the prescribed target pressure 502, which is the filtered withdrawal occlusion pressure limit (PwOccFilt), by adjusting the blood pump flow rate.</p> <p>Col. 10: 38-41: Signals from the air detector and/or blood leak detector may be transmitted to the controller, which in turn issues an alarm if a blood leak or air is detected in the ultrafiltrate or blood tubing passages of the extracorporeal circuit.</p> <p>Col. 12:39-41: After the blood passes through the ultrafiltrate filter 108, it is pumped through</p>

		<p>a two meter infusion return tube 105 to the infusion needle 103 where it is returned to the patient.</p> <p>Col. 15: 66-67: The occlusion and disconnect pressure limits for the return (infusion) line are graphically shown in FIGURE 6.</p> <p>Col. 19:18-21: The maximum occlusion pressure algorithm 601 is a positive relationship between the flow rate (Q_b) and infusion pressure (P_{in}) as measured by the pressure sensor in the return line 110.</p> <p>Col. 5: 54-57: In the event of a withdrawal pressure occlusion that terminates flow, the flow controller will temporarily reverse the flow of the pump in an attempt to remove the withdrawal occlusion.</p> <p>Col. 18: 18-24.: When the blood pump is reversed, the withdrawal and infusion disconnect and occlusion algorithms are still active protecting the patient from exposure to high pressures and disconnects. When the blood pump flow is reversed the occlusion limits and disconnect limits are inverted by multiplying by negative 1. This allows the pump to reverse while still being controlled by maximum pressure limits.</p> <p>Col. 10: 33-36: As the blood is pumped through the circuit, an air detector 117 monitors for the presence of air in the blood circuit.</p>
38	2	<p>Col. 18:18-24.: When the blood pump is reversed, the withdrawal and infusion disconnect and occlusion algorithms are still active</p> <p>Col. 18:28-39: Two (2) ml of blood may be</p>

		<p>infused into the withdrawal line and into the withdrawal peripheral vein by reversing the blood pump at 20 ML/min to ensure that the vein is not collapsed. The blood pump is stopped for 2 seconds and withdrawal is reinitiated.</p> <p>Col. 18: 36-39: The blood circuit has a total volume of approximately 60 ml. The blood pump is limited to reversing a total volume of five ml thereby minimizing the possibility of infusing the patient with air.</p> <p>Col. 25:24-27: The control system allowed reversed flow continued for 1 second at 10 mL/min as programmed into an algorithm. This resulted in possible re-infusion of 0.16 mL of blood back into the withdrawal vein. These parameters were set for the experiment and may not reflect an optimal combination.</p>
39	3	<p>Col. 5:54-57: In the event of a withdrawal pressure occlusion that terminates flow, the flow controller will temporarily reverse the flow of the pump in an attempt to remove the withdrawal occlusion.</p> <p>Col. 18:18-24: When the blood pump is reversed, the withdrawal and infusion disconnect and occlusion algorithms are still active protecting the patient from exposure to high pressures and disconnects. When the blood pump flow is reversed the occlusion limits and disconnect limits are inverted by multiplying by negative 1. This allows the pump to reverse while still being controlled by maximum pressure limits.</p> <p>Col 25: 15-27 ...illustrated by FIG. 8,... the rapid reduction of the blood flow 804 by the control system in response to the decreasing (more negative) withdrawal pressure 802</p>

		<p>prevented escalation of the occlusion, but resulted in crossing of the occlusion limit 803 into positive values at the point 902. Simultaneously the blood flow 804 dropped to zero and sequentially became negative (reversed direction) for a short duration of time 903. The control system allowed reversed flow continued for 1 second at 10 mL/min as programmed into an algorithm. This resulted in possible re-infusion of 0.16 mL of blood back into the withdrawal vein. These parameters were set for the experiment</p> <p>Col. 25:33-37 During the short period of time when the blood flow in the circuit was reversed, occlusion limits and algorithms in both infusion and withdrawal limbs of the circuit remained active. The polarity of the limits was reversed in response to the reversed direction of flow and corresponding pressure gradients.</p>
40	5	<p>Col. 8: 34-43: The controller may regulate blood withdrawn from a peripheral vein to a flow rate in a normal range of 0 to 150 ml/min (milliliters per minute). An operator may select a maximum withdrawal flow rate within this normal pressure range at which the blood filtering system is to operate. The controller will maintain the flow rate at or near the desired flow rate, provided that there is compliance with a pressure vs. flow rate limit control algorithm.</p> <p>Col. 8: 59-64 The controller optimizes blood flow at or below a preset maximum flow rate in accordance with one or more pressure vs. flow algorithms. These algorithms may be stored in memory of the controller which includes a processor, e.g., microprocessor; memory for data and program storage; input/output (I/O) devices for interacting with</p>

	<p>a human operator, for receiving feedback signals, e.g., pressure signals, from the blood circuit and possibly other systems, e.g., patient condition, and for issuing commands to control the pump speed; and data busses to allow the controller components to communicate with one another.</p> <p>Col. 8: 59-64 The control algorithms may include (without limitations): maximum flow settings for an individual patient treatment that is entered by the operator, a data listing of acceptable withdrawal/line pressures for each of a series of flow rates, and mathematical equations, e.g., linear, which correlates acceptable pressure to a flow rate.</p> <p>Col 11 Line 5-17: The roller blood pump 113 is rotated by a brushless DC motor housed within the console 106. The pump includes a rotating mechanism with orbiting rollers that are applied to a half-loop 119 in the blood passage tubing of the blood circuit. The orbital movement of the rollers applied to tubing forces blood to move through the circuit. This half-loop segment may have the same ID as does the other blood tubing portions of the blood circuit. The pump may displace approximately 1 ml (milliliter) of blood through the circuit for each full orbit of the rollers. If the orbital speed of the pump is 60 RPM (revolutions per minute), then the blood circuit may withdraw 60 ml/min of blood, filter the blood and return it to the patient.</p> <p>Col. 16: 55-64 FIG. 5 includes a functional diagram of a PIFF (Proportional Integral Feed Forward) pressure controller 501 for the ultrafiltration apparatus 100, and shows how</p>
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		<p>the PIFF operates to control pressure and flow of blood through the circuit.</p> <p>Controllers of the PIFF type are well known in the field of "controls engineering". The PIFF pressure controller 501 controls the withdrawal pressure to the prescribed target pressure 502, which is the filtered withdrawal occlusion pressure limit (PwOccFilt), by adjusting the blood pump flow rate.</p> <p>Col. 17: 6-9 and 22-24 The PIFF determines the appropriate total flow rate (Qtotal) based on the difference signal 505, the current flow rate, the current rate of increase or decrease of the flow rate, and the flow rate limit.</p> <p>Col. 17: 23-25 This desired flow rate (Qtotal) is then applied to control the blood pump speed, and, in turn, the actual flow rate through the blood circuit.</p> <p>Col. 19: 47-51 The controller CPU regulates the pump speeds by commanding a motor controller 702 to set the rotational speed of the blood pump 113 to a certain speed specified by the controller CPU.</p> <p>Col. 14: 47-59: The blood flow (QbMeas) may be determined by the controller, e.g., controller CPU, based on the rotational speed of the blood pump and the known volume of blood that is pumped with each rotation of that pump, as is shown in the equation below:</p> $PwOcc=QbMeas*KwO+B$ <p>Where QbMeas is the measured blood flow, KwO is the withdrawal occlusion control algorithm 302, e.g., a linear slope of flow vs. pressure, and B is a pressure offset applied to the withdrawal occlusion, which</p>
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		<p>offset is described below.</p> <p>The expression for PwOcc is a linear equation to describe. PwOcc may also be implemented as a look up table where a known QbMeas is entered to obtain a value for PwOcc.</p>
41	6	<p>Col. 10: 33-36: As the blood is pumped through the circuit, an air detector 117 monitors for the presence of air in the blood circuit.</p>
42	7	<p>Col. 5: 54-57: In the event of a withdrawal pressure occlusion that terminates flow, the flow controller will temporarily reverse the flow of the pump in an attempt to remove the withdrawal occlusion.</p> <p>Col. 18: 18-24.: When the blood pump is reversed, the withdrawal and infusion disconnect and occlusion algorithms are still active protecting the patient from exposure to high pressures and disconnects. When the blood pump flow is reversed the occlusion limits and disconnect limits are inverted by multiplying by negative 1. This allows the pump to reverse while still being controlled by maximum pressure limits.</p> <p>Col. 10: 33-36 As the blood is pumped through the circuit, an air detector 117 monitors for the presence of air in the blood circuit.</p>
43	13	<p>Col. 3: 31-33 A blood flow controller has been developed that controls blood flow through an extracorporeal blood circuit</p> <p>Col. 8: 59-66. The control algorithms may include (without limitations): maximum flow settings for an individual patient treatment that</p>

	<p>is entered by the operator, a data listing of acceptable withdrawal/line pressures for each of a series of flow rates, and mathematical equations, e.g., linear, which correlates acceptable pressure to a flow rate. The algorithms may be determined for each particular make or model of an extraction and infusion extracorporeal blood system</p> <p>Col. 10: 8-13 The circuit may come in a sterile package and is intended that each circuit be used for a single treatment.</p> <p>Col. 10: 38-41 Signals from the air detector and/or blood leak detector may be transmitted to the controller, which in turn issues an alarm if a blood leak or air is detected in the ultrafiltrate or blood tubing passages of the extracorporeal circuit.</p> <p>Col. 20: 16-20 The monitoring CPU 714 provides a safety check that independently monitors each of the critical signals, including signals indicative of blood leaks, pressures in blood circuit, weight of filtrate bag, motor currents, air in blood line detector and motor speed/position.</p> <p>Col. 25: 15-27 ...illustrated by FIG. 8, the rapid reduction of the blood flow 804 by the control system in response to the decreasing (more negative) withdrawal pressure 802 prevented escalation of the occlusion, but resulted in crossing of the occlusion limit 803 into positive values at the point 902. Simultaneously the blood flow 804 dropped to zero and sequentially became negative (reversed direction) for a short duration of time 903. The control system allowed reversed flow continued for 1 second at 10 mL/min as programmed into an algorithm. This resulted in possible re-infusion of 0.16 mL of blood back</p>
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		<p>into the withdrawal vein. These parameters were set for the experiment and may not reflect an optimal combination.</p> <p>Col. 10: 33-36: As the blood is pumped through the circuit, an air detector 117 monitors for the presence of air in the blood circuit.</p> <p>Col. 10: 38-41 Signals from the air detector and/or blood leak detector may be transmitted to the controller, which in turn issues an alarm if a blood leak or air is detected in the ultrafiltrate or blood tubing passages of the extracorporeal circuit.</p> <p>Col. 20: 17-20 The monitoring CPU 714 provides a safety check that independently monitors each of the critical signals, including signals indicative of blood leaks, pressures in blood circuit, weight of filtrate bag, motor currents, air in blood line detector and motor speed/position</p> <p>Col. 14: 33-37 A disconnection is detected when the pressure P_w at a given blood flow is greater than the pressure described by curve 303, and if air is detected in the blood circuit</p> <p>Col. 3: 31-44 A blood flow controller has been developed that controls blood flow through an extracorporeal blood circuit. The controller regulates the flow rate through the circuit such that: (a) blood is withdrawn from a peripheral vein in the patient (which veins are usually small, collapsible tubes) at a blood flow rate sustainable by the vein and which avoids collapsing the vein, and (b) blood pressure changes in the circuit are compensated for by adjusting pump speed and hence the flow rate through the circuit. The controller sets a flow rate of blood through the</p>
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		<p>circuit based on both a maximum flow rate limit and a variable limit of pressure vs. flow rate. These limits may be preprogrammed in the controller and/or selected by an operator.</p> <p>Col. 8: 59-66 The control algorithms may include (without limitations): maximum flow settings for an individual patient treatment that is entered by the operator, a data listing of acceptable withdrawal/line pressures for each of a series of flow rates, and mathematical equations, e.g., linear, which correlates acceptable pressure to a flow rate. The algorithms may be determined for each particular make or model of an extraction and infusion extracorporeal blood system</p> <p>Col. 10: 33-36: As the blood is pumped through the circuit, an air detector 117 monitors for the presence of air in the blood circuit.</p> <p>Col. 20: 17-20 The monitoring CPU 714 provides a safety check that independently monitors each of the critical signals, including signals indicative of blood leaks, pressures in blood circuit, weight of filtrate bag, motor currents, air in blood line detector and motor speed/position</p>
44	14	<p>Col. 18: 17-24 When the blood pump stops, the blood flow is reversed and blood is pumped into the withdrawal vein in an attempt to open that vein. When the blood pump is reversed, the withdrawal and infusion disconnect and occlusion algorithms are still active protecting the patient from exposure to high pressures and disconnects. When the blood pump flow is reversed the occlusion limits and disconnect limits are inverted by multiplying by negative 1. This allows the</p>

		<p>pump to reverse while still being controlled by maximum pressure limits.</p> <p>Col. 6: 57-69 FIG. 5 is a flow chart of an algorithm showing a blood withdrawal and infusion PIFF pressure control algorithm to be implemented by the controller.</p> <p>Col. 25: 15-27 ...illustrated by FIG. 8, the rapid reduction of the blood flow 804 by the control system in response to the decreasing (more negative) withdrawal pressure 802 prevented escalation of the occlusion, but resulted in crossing of the occlusion limit 803 into positive values at the point 902. Simultaneously the blood flow 804 dropped to zero and sequentially became negative (reversed direction) for a short duration of time 903. The control system allowed reversed flow continued for 1 second at 10 mL/min as programmed into an algorithm. This resulted in possible re-infusion of 0.16 mL of blood back into the withdrawal vein. These parameters were set for the experiment and may not reflect an optimal combination.</p>
45	16	<p>Col. 10: 33-36: As the blood is pumped through the circuit, an air detector 117 monitors for the presence of air in the blood circuit.</p>
46	18	<p>See support cited for claim 43, in addition:</p> <p>Col. 10: 38-41: Signals from the air detector and/or blood leak detector may be transmitted to the controller, which in turn issues an alarm if a blood leak or air is detected in the ultrafiltrate or blood tubing passages of the extracorporeal circuit.</p> <p>Col. 12:39-41: After the blood passes through the ultrafiltrate filter 108, it is pumped through</p>

		<p>a two meter infusion return tube 105 to the infusion needle 103 where it is returned to the patient.</p> <p>Col. 15: 66-67: The occlusion and disconnect pressure limits for the return (infusion) line are graphically shown in FIGURE 6.</p> <p>Col. 16: 60-64: The PIFF pressure controller 501 controls the withdrawal pressure to the prescribed target pressure 502, which is the filtered withdrawal occlusion pressure limit (PwOccFilt), by adjusting the blood pump flow rate.</p> <p>Col. 19:18-21: The maximum occlusion pressure algorithm 601 is a positive relationship between the flow rate (Qb) and infusion pressure (Pin) as measured by the pressure sensor in the return line 110.</p> <p>Col. 19:47-51: The controller CPU regulates the pump speeds by commanding a motor controller 702 to set the rotational speed of the blood pump 113 to a certain speed specified by the controller CPU.</p> <p>Col. 5: 54-57: In the event of a withdrawal pressure occlusion that terminates flow, the flow controller will temporarily reverse the flow of the pump in an attempt to remove the withdrawal occlusion.</p> <p>Col. 18: 18-24.: When the blood pump is reversed, the withdrawal and infusion disconnect and occlusion algorithms are still active protecting the patient from exposure to high pressures and disconnects. When the blood pump flow is reversed the occlusion limits and disconnect limits are inverted by</p>
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47	20	<p>Col. 5: 54-57: In the event of a withdrawal pressure occlusion that terminates flow, the flow controller will temporarily reverse the flow of the pump in an attempt to remove the withdrawal occlusion.</p> <p>Page 32 line 29 and page 33 line 1 to 5 of application: Col. 18: 18-24.: When the blood pump is reversed, the withdrawal and infusion disconnect and occlusion algorithms are still active protecting the patient from exposure to high pressures and disconnects. When the blood pump flow is reversed the occlusion limits and disconnect limits are inverted by multiplying by negative 1. This allows the pump to reverse while still being controlled by maximum pressure limits.</p> <p>Col. 25: 15-27 ...illustrated by FIG. 8, the rapid reduction of the blood flow 804 by the control system in response to the decreasing (more negative) withdrawal pressure 802 prevented escalation of the occlusion, but resulted in crossing of the occlusion limit 803 into positive values at the point 902. Simultaneously the blood flow 804 dropped to zero and sequentially became negative (reversed direction) for a short duration of time 903. The control system allowed reversed flow continued for 1 second at 10 mL/min as programmed into an algorithm. This resulted in possible re-infusion of 0.16 mL of blood back into the withdrawal vein. These parameters</p>

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50	42	<p>Col. 8: 59-66 The control algorithms may include (without limitations): maximum flow settings for an individual patient treatment that is entered by the operator, a data listing of acceptable withdrawal/line pressures for each of a series of flow rates, and mathematical equations, e.g., linear, which correlates acceptable pressure to a flow rate. The algorithms may be determined for each particular make or model of an extraction and infusion extracorporeal blood system</p> <p>Col. 10: 38-41 Signals from the air detector and/or blood leak detector may be transmitted</p>

		<p>to the controller, which in turn issues an alarm if a blood leak or air is detected in the ultrafiltrate or blood tubing passages of the extracorporeal circuit.</p> <p>Col. 20: 17-20 The monitoring CPU 714 provides a safety check that independently monitors each of the critical signals, including signals indicative of blood leaks, pressures in blood circuit, weight of filtrate bag, motor currents, air in blood line detector and motor speed/position</p> <p>Col. 5: 54-57: In the event of a withdrawal pressure occlusion that terminates flow, the flow controller will temporarily reverse the flow of the pump in an attempt to remove the withdrawal occlusion.</p> <p>Col. 18: 18-24.: When the blood pump is reversed, the withdrawal and infusion disconnect and occlusion algorithms are still active protecting the patient from exposure to high pressures and disconnects. When the blood pump flow is reversed the occlusion limits and disconnect limits are inverted by multiplying by negative 1. This allows the pump to reverse while still being controlled by maximum pressure limits.</p> <p>Col. 10: 33-36 As the blood is pumped through the circuit, an air detector 117 monitors for the presence of air in the blood circuit.</p>
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61	60	<p>Col. 8: 59-66 The control algorithms may include (without limitations): maximum flow settings for an individual patient treatment that is entered by the operator, a data listing of acceptable withdrawal/line pressures for each of a series of flow rates, and mathematical equations, e.g., linear, which correlates acceptable pressure to a flow rate. The algorithms may be determined for each particular make or model of an extraction and infusion extracorporeal blood system.</p> <p>Reverse flow: Col. 5: 54-57; Col. 18: 18-24; Col. 25:24-27 and Col. 25: 15-27.</p> <p>Col. 10: 33-36: As the blood is pumped through the circuit, an air detector 117 monitors for the presence of air in the blood circuit.</p>

62	61	<p>Col. 18: 18-24.: When the blood pump is reversed, the withdrawal and infusion disconnect and occlusion algorithms are still active protecting the patient from exposure to high pressures and disconnects. When the blood pump flow is reversed the occlusion limits and disconnect limits are inverted by multiplying by negative 1. This allows the pump to reverse while still being controlled by maximum pressure limits.</p>
63	62	<p>Col. 19:47-51: The controller CPU regulates the pump speeds by commanding a motor controller 702 to set the rotational speed of the blood pump 113 to a certain speed specified by the controller CPU.</p> <p>Col. 16: 60-64: The PIFF pressure controller 501 controls the withdrawal pressure to the prescribed target pressure 502, which is the filtered withdrawal occlusion pressure limit (PwOccFilt), by adjusting the blood pump flow rate.</p> <p>Col. 10: 38-41: Signals from the air detector and/or blood leak detector may be transmitted to the controller, which in turn issues an alarm if a blood leak or air is detected in the ultrafiltrate or blood tubing passages of the extracorporeal circuit.</p> <p>Col. 12:39-41: After the blood passes through the ultrafiltrate filter 108, it is pumped through a two meter infusion return tube 105 to the infusion needle 103 where it is returned to the patient.</p> <p>Col. 15: 66-67: The occlusion and disconnect pressure limits for the return (infusion) line are graphically shown in FIGURE 6.</p> <p>Col. 19:18-21: The maximum occlusion pressure algorithm 601 is a positive</p>

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67	73	<p>Col. 10: 33-36: As the blood is pumped through the circuit, an air detector 117 monitors for the presence of air in the blood circuit.</p>
68	81	<p>Col. 19:47-51: The controller CPU regulates the pump speeds by commanding a motor controller 702 to set the rotational speed of the blood pump 113 to a certain speed specified by the controller CPU.</p> <p>Col. 16: 60-64: The PIFF pressure controller 501 controls the withdrawal pressure to the prescribed target pressure 502, which is the filtered withdrawal occlusion pressure limit (PwOccFilt), by adjusting the blood pump flow rate.</p> <p>Col. 10: 38-41: Signals from the air detector and/or blood leak detector may be transmitted to the controller, which in turn issues an alarm if a blood leak or air is detected in the</p>

	<p>ultrafiltrate or blood tubing passages of the extracorporeal circuit.</p> <p>Col. 12:39-41: After the blood passes through the ultrafiltrate filter 108, it is pumped through a two meter infusion return tube 105 to the infusion needle 103 where it is returned to the patient.</p> <p>Col. 15: 66-67: The occlusion and disconnect pressure limits for the return (infusion) line are graphically shown in FIGURE 6.</p> <p>Col. 19:18-21: The maximum occlusion pressure algorithm 601 is a positive relationship between the flow rate (Q_b) and infusion pressure (P_{in}) as measured by the pressure sensor in the return line 110.</p> <p>Col. 5: 54-57: In the event of a withdrawal pressure occlusion that terminates flow, the flow controller will temporarily reverse the flow of the pump in an attempt to remove the withdrawal occlusion.</p> <p>Col. 18: 18-24.: When the blood pump is reversed, the withdrawal and infusion disconnect and occlusion algorithms are still active protecting the patient from exposure to high pressures and disconnects. When the blood pump flow is reversed the occlusion limits and disconnect limits are inverted by multiplying by negative 1. This allows the pump to reverse while still being controlled by maximum pressure limits.</p> <p>Col. 10: 33-36: As the blood is pumped through the circuit, an air detector 117 monitors for the presence of air in the blood circuit.</p>
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69	82	Col. 10: 33-36: As the blood is pumped through the circuit, an air detector 117 monitors for the presence of air in the blood circuit.
70	85	Col. 18: 18-24.: When the blood pump is reversed, the withdrawal and infusion disconnect and occlusion algorithms are still active protecting the patient from exposure to high pressures and disconnects.
71	86	<p>Col. 19:47-51: The controller CPU regulates the pump speeds by commanding a motor controller 702 to set the rotational speed of the blood pump 113 to a certain speed specified by the controller CPU.</p> <p>Col. 16: 60-64: The PIFF pressure controller 501 controls the withdrawal pressure to the prescribed target pressure 502, which is the filtered withdrawal occlusion pressure limit (PwOccFilt), by adjusting the blood pump flow rate.</p> <p>Col. 10: 38-41: Signals from the air detector and/or blood leak detector may be transmitted to the controller, which in turn issues an alarm if a blood leak or air is detected in the ultrafiltrate or blood tubing passages of the extracorporeal circuit.</p> <p>Col. 12:39-41: After the blood passes through the ultrafiltrate filter 108, it is pumped through a two meter infusion return tube 105 to the infusion needle 103 where it is returned to the patient.</p> <p>Col. 15: 66-67: The occlusion and disconnect pressure limits for the return (infusion) line are graphically shown in FIGURE 6.</p> <p>Col. 19:18-21: The maximum occlusion pressure algorithm 601 is a positive relationship between the flow rate (Qb) and</p>

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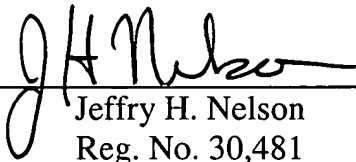
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73	23	Inherent in operation of a peristaltic pump.
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All claims are in good condition for allowance. If any small matter remains outstanding, the Examiner is requested to telephone the undersigned. Prompt reconsideration and allowance of this application is requested.

Respectfully submitted,

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